

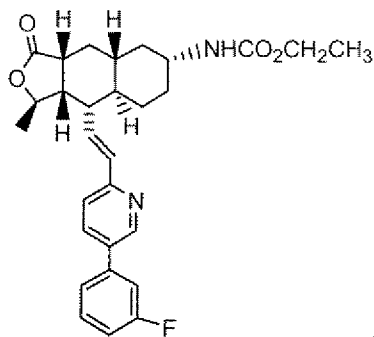
REMARKS/ARGUMENTS

Status of the Claims

Claims 1-8, 11-16, 19-27 and 29-43 were pending in this application. Claims 1-39 are cancelled. Claims 44-55 are herein added. Thus, after entry of this Amendment, Claims 40-55 will be under examination on the merits.

New Claims

Claims 44-55 are herein added. These claims are directed to methods of treating acute coronary syndrome in a patient in need thereof comprising orally administering to said patient a therapeutically effective amount of the thrombin receptor antagonist of the formula



(Claims 44-46) or a pharmaceutically acceptable isomer (Claims 47-49), salt (Claims 50-52) or solvate (Claims 53-55) thereof, in a solid pharmaceutical composition. As these claims are closely related to previously presented Claims 40-43, Applicants submit that no new search is warranted, and that the new claims are in condition for allowance along with the previously presented claims, as explained below.

No new matter has been added to the application. Applicants reserve the right to pursue unelected subject matter in divisional applications, and unclaimed subject matter within the elected invention in continuation applications.

Correction of Inventorship

The cancellation of claims 1-39, and addition of claims 44-55 has resulted the pendency of only claims 40-55. Consequently, only Enrico P. Veltri remains as an inventor of the pending claims. Thus, Applicants herewith file a Request to Correct Inventorship under C.F.R. §1.48(b).

Specification

The Abstract was objected to on the grounds that it included legal phraseology, specifically the word "said," and that it comprised more than a single paragraph. The same objection was lodged in the Office Action mailed on March 23, 2007.

In their Amendment responsive to the Office Action mailed on March 23, 2007, Applicants had amended the Abstract to substitute the word "the" for the word "said" and to combine the material from the two paragraphs into a single paragraph, thus overcoming the objection. (See p. 2 of Amendment dated September 21, 2007).

It appears that the amendment of the Abstract was overlooked in repeating the objection in the Office Action dated December 12, 2007.

Claim Rejections – 35 USC §103

Claims 40-43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chackalamannil *et al* (U.S. Pat. No. 6,063,847, "the '847 patent") in view of Gerlitz *et al* (U.S. 2003/0022354).

The '847 patent was characterized in the Office Action as disclosing a set of structurally homologous compounds that render the compound of Claim 40 *prima facie* obvious, absent a showing of unexpected results.

Applicants respectfully rebut any *prima facie* obviousness case.

As a matter of background, the compound of Claim 40 was first claimed as a composition of matter in U.S. Pat. No. 7,304,078 ("the '078 patent"). Applicants noted this in their Amendment dated September 21, 2007 at p. 20 as follows:

Applicants point out that, *the compound of Claim 40 is disclosed and claimed in co-pending application no. 10/412,982, the corresponding PCT application no WO03/089428 having published on November 3, 2003.*
(Emphasis as in original.)

This application is referenced in the specification of the present application at p. 1, line 11, and its publication (U.S. Pub. No. 20030216437) was disclosed in the Information Disclosure Statement submitted on June 8, 2005.

In accordance with the guidance given in McKesson Info. Solutions, Inc. v. Bridge Med. Inc., 487 F.3d 897 (Fed. Cir. 2007), Applicants herewith submit the

complete file history of the '078 patent along with an Information Disclosure Statement and the associated Form PTO/SB/08b.

Applicants rebut the *prima facie* obviousness case on two grounds. First, the Office Action provides no basis for the proposition necessary to a *prima facie* case that it would have been obvious to one skilled in the art to select for the right-hand ring substituent a primary amine derivative in view of the lengthy list of substituents claimed in the '847 patent.

Second, the specification of the '078 patent provides a basis for the proposition that the compounds claimed therein possess superior properties to those claimed in the '847 patent. "A *prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties." Manual of Patent Examining Procedure, rev. 3, August 2005, §2144.09, p. 2100-165, *citing In re Papesch*, 315 F.2d 381 (CCPA 1963).

The specification of the '078 patent addresses the relationship between the properties of the compounds claimed therein and the properties of those disclosed in the '847 patent as follows:

Compounds of the present invention are surprisingly active in the ex-vivo platelet aggregation test model. In these studies, the compound of Example 2 of this invention, after oral administration at a dose of 0.1 mg/kg, completely inhibited aggregation of platelets induced by exogenously added thrombin receptor activating peptide for duration of 24 hours. Even after 48 hours, approximately 65% of inhibition of platelet aggregation was sustained. *In contrast, N-alkyl carbamate analogs, Examples 1A and 2A of US 6,063,847 were studied under similar conditions using a dose of 0.5 mg/kg, a 5-fold increase over the dose of the compound of Example 2. Under these conditions, the N-alkyl compounds showed no significant inhibition of platelet aggregation at various time points.*

U.S. Pat. No. 7,304,078, p. 50 (emphasis added).

The compound of Example 2 of the '078 patent is the compound of Claim 40 herein. The above statement makes it clear that, at least in the two comparisons made (Examples 1A and 2A), the compound of Claim 40 possesses unexpectedly advantageous or superior properties with respect to those claimed in the '847 patent.

It is on these grounds that Applicants respectfully rebut any *prima facie* case of obviousness.

Claim Rejections – Statutory-Type Double Patenting

Claim 40 is rejected under 35 U.S.C. §101 as claiming the same invention as that of Claims 25, 28, 33, 38, 43, 53, and 58 of Chackalamannil *et al* (U.S. Pat. No. 7,304,078) as evidenced by Gerlitz *et al* (U.S. 2003/0022354). It was stated that Gerlitz teaches that myocardial infarction is a specific type of acute coronary syndrome, and that any method that is directed to treating myocardial infarction can also treat acute coronary syndrome.

Applicants stipulate to the Examiner's contention that acute coronary syndrome is a genus of symptoms, and that myocardial infarction is a species within that genus.

Applicants contend that the claim to treatment of a genus of symptoms is not for the purposes of 35 U.S.C. §101 the same invention as a claim to treatment of a species within that genus. Thus, the claims the Examiner has identified as conflicting are not coextensive in scope. On this basis, Applicants traverse the statutory-type double patenting rejection as improper.

Claim Rejections – Obviousness-Type Double Patenting

Claim 40 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1 and 18 of Chackalamannil *et al* (U.S. Pat. No. 6,063,847) as evidenced by Gerlitz *et al* (U.S. 2003/0022354).

As indicated above, Applicants stipulate to the Examiner's contention that acute coronary syndrome is a genus of symptoms, and that myocardial infarction is a species within that genus.

Applicants contend that the claim to treatment of a genus of symptoms can not be rendered unpatentable for obviousness-type double patenting in view of a disclosure of treatment of a species within that genus. On this basis, Applicants maintain that the obviousness-type double patenting rejection is improper.

Claim 40 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-4, 9 and 16 of co-pending application to Veltri *et al* (U.S. Ser. No. 11/613,450, "the '450 application").

The '450 application was filed on December 20, 2006, and claims the benefit to provisional application no. 60/753,246, filed Dec. 22, 2005. The present application was filed on November 10, 2003. Thus, the '450 application, which was filed later and has a priority date later than the filing date of the present application, does not qualify as prior art that can be properly cited as the grounds of a rejection for nonstatutory obviousness-type double patenting. On this basis, Applicants maintain that the rejection is improper.

However, in the interest of facilitating examination and removing these references as grounds for nonstatutory obviousness-type double patenting rejections, Applicants herewith submit Terminal Disclaimers over each of U.S. Pat. No. 6,063,847 and U.S. Ser. No. 11/613,450.

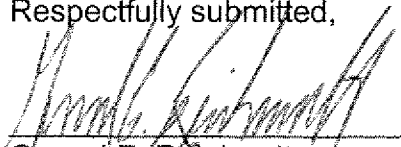
In view of the above, Applicants submit that the application is in condition for allowance, which allowance is earnestly sought.

AUTHORIZATION

The Final Office Action to which this paper is responsive was mailed on December 12, 2007, with a shortened statutory period for reply set to expire three months thereafter, on March 12, 2008. This Response is transmitted prior to expiration of the two-month extension of this date, and thus Applicants authorize the Commissioner to draw the requisite fee from Applicants' deposit account no. 19-0365. Should any further such fee become necessary to allow consideration of the remarks herein and render this Response timely filed, the Commissioner is authorized to draw the required amount from Applicants' deposit account no. 19-0365.

May 12, 2008

Respectfully submitted,


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